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April 1, 1991

MEMORANDUM TO TOBACCO INSTITUTE FILE

Re: A Presentation by Dr. S. Bayard
at the Biometrics Society Meeting
in Houston, March 25, 1991

INTRODUCTION

Dr. Steven Bayard of EPA, presented a paper entitled "Risk Assessment of Passive Smoking" (co-authors Brown and Thorslund) at the Biometrics Society Meeting in Houston on March 25. The abstract for this paper is attached. This memorandum highlights salient points from the presentation, and reports on a conversation involving Ms. Kay Thomas, Dr. Maurice LeVois and the undersigned with Bayard directly after his talk.

BAYARD'S PRESENTATION

Bayard introduced the subject of ETS by referring to the Draft Report released by EPA in June 1990. He described this document as being released for public comment, reviewed by the SAB and now currently being revised for a release this summer.

The presentation was then, apparently, a repeat of a paper given by Dr. Ken Brown at the Society for Risk Analysis annual meeting in October 1990. This simply reiterated the approach laid out in the EPA Draft Report.

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Bayard suggested that the classification of ETS a Group A carcinogen had to be based upon there being sufficient epidemiological evidence. Within the epidemiological data, there should be no identified bias, the possibility of confounding factors should be considered and ruled out, and it must be that the association is unlikely to be due to chance.

In examining the 24 epidemiological studies considered, Bayard suggested that the surrogate of exposure, spousal smoking, was problematic in that this surrogate does not cover total exposure. He gave credence to a paper by Janerich in the New England Journal of Medicine that claimed that one-third of exposure occurs before age 18, another third from spousal smoking and a final third from workplace exposure.

Bayard suggested that the work of Hirayama was the "classic study", that there were many more studies, but that there was very little power for most. He stated that the studies had considerable differences in methodology, and that in many cases the data had to be adjusted before combination. He gave the impression that the element that convinced him most about the epidemiology was the consistency in the dose-response, whether this be judged using numbers of cigarettes smoked or years of smoking by spouse.

In terms of possible biases within the epidemiological studies, Bayard said that there were five factors:

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a) Misclassification of smoking status (+ ve systematic bias);

b) Background exposure for unexposed subjects (- ve systematic bias);

c) Misdiagnosis of primary cancer site;

d) Systematic error in proxy responses; and

e) Publication bias.

Bayard stated that c, d and e were unimportant. As for background exposure corrections, he suggested that non-smokers exposed to spousal smoking had three times the level of urinary cotinine of those not so exposed, and hence non-spousally exposed non-smoker controls were exposed to one-third of that of cases.

From the combined estimates, Bayard stated that 26% of non-smoking lung cancer deaths are due to ETS exposure. By assuming 60% of non-smoking females live with a smoker, he suggested 2,210 female and 1,470 male deaths per year (total 3,800).

In a somewhat hurried presentation, Bayard then ran out of time to talk about low dose extrapolation. Instead, he concluded by presenting the EPA's current direction, which divided into three points:

1. The inclusion of additional ETS epidemiological studies in the meta-analysis;

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2. Adjustments for both misclassification, background exposure and the effect of B-carotene are to be done on an individual country basis; and

3. A dose-response model based on mainstream smoking and cigarette equivalent doses of ETS will be further developed.

The conference did not allow for direct questioning of the speakers. However, in a 15-minute session, Dr. Ralph Kodell of the National Center for Toxicological Research, commented on Bayard's presentation.

REVIEW BY KODELL

Kodell's review basically agreed with Bayard's presentation, though he was uncertain as to whether the data was sufficient to permit a Group A classification. In particular, he stated that the "failure" of the American (Garfinkel) study to show significance was highly "disconcerting."

Kodell recommended that a "further review of the American study was necessary," and that if it did not support the conclusion of Group A classification, then there should be an explanation as to why not.

CONVERSATION WITH BEYOND AFTER THE PRESENTATION

Ms. Thomas, Dr. LeVois and the undersigned cornered Bayard for around 30 minutes after the session. Dr. LeVois

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emphasized several points on the science of both the meta-analysis and the low-dose extrapolation. In particular, it was suggested to Bayard that:

1. Confounding factors related to concordance (life style factors within married couples) can easily be related to dose response effects. Bayard said that he had never seen any data on this. LeVois will send some.

2. In testing dose response relationships, the "no effect, no dose" group should be omitted. Again Bayard denied knowledge of this, and again LeVois will follow up.

I questioned on the status of the SAB report and related issues. The information that I received may be summarized as follows:

1. Bayard received the Draft Report from the SAB on Monday, March 18. As yet, he had read only one half of what he said to be a 70 or 90-page document.

2. His impression of the report was that it agreed with the classification to Group A, but that it did not agree with using the ETS epidemiology to make this case.

3. Bayard said, "I should not be telling you this, but I will anyway. The report says that I should forget the epidemiology and concentrate on mainstream, and that if this created a problem with guidelines for classification, then they (the guidelines) should be changed." I

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suggested that surely this would cause him considerable problems with other issues EPA may be called upon to address.

4. On asking Bayard whether a summer deadline was realistic, he responded with uncertainty but suggested that he would be trying to make this timeframe.

5. I asked where he would get the data for the individual country adjustments. He said that this would be based on the IARC study and that Riboli had promised him some additional data. Bayard said that he would send this information to me if Riboli gave permission.

6. We also asked Bayard what additional studies was he considering. He said that involved Janerich, Butler (I believe this to be a thesis on California Seventh Day Adventists) and another that he could not remember (perhaps data from Kabat?). On asking him about the Wu-Williams paper, he said he did not know of it. I said that I would send it to him.

7. I also asked him whether he was involved with EMF. He said not, that he was doing some interesting work on asbestos particle sizes, and that his next project would be on dioxins.

Chris Proctor

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